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(71)(72) Applicant and Inventor: WEIBEL, Stig, Eric [DK/DK]; Boserupvej 119, DK-3050 Humlebæk (DK).

(74) Agent: LEHMANN & REE; Frederiksberg Allé 26, DK-1820 Frederiksberg C (DK).

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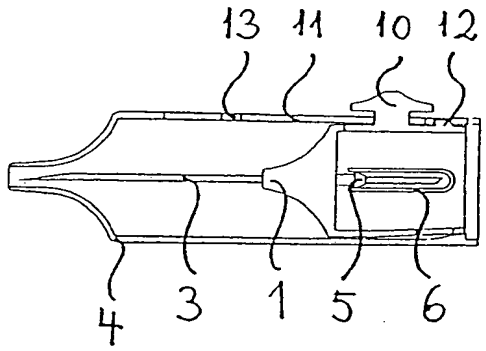

(57) Abstract

A device for taking blood samples comprising a holder (1) for a blood sample tube (2), the holder (1) carrying a needle (3) and being mounted in a safety shield (4) in a way enabling its axial displacement relative to the shield (4) between a blood sample taking position, the point of the needle (3) projecting from the shield (4), and a protective position, the needle (3) being completely confined in the safety shield (4). The axial displacement of the holder (1) is obtained by means of a finger grip element (10) at the holder (1), this grip (10) being movable in a slot (11) in the shield (4). Fixing of the holder (1) in the end positions is obtained by using the same grip (10). The blood sample device may be provided with slot-formed openings in the shield, enabling the holding with the hand of the tube (2) during the blood sample taking, with a further holder for tubes (2) with smaller diameter, with an internal threaded bottom of the holder (1), enabling use of a separate needle and/or with a holder (1), which is activated by a spring.

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BLOOD TAKING DEVICE

When taking a blood sample according to the generally known procedure, the so-called "closed system procedure", the blood is brought to flow from a vein, passing a double needle placed in a blood sample device, into an evacuated blood sample tube, this blood sample tube supplying the vacuum being required to promote the flow of the blood from the vein, through the double needle and into the blood sample tube.

The double needle and the blood sample device are generally screwed together before use, and following use these two parts are again disconnected and discarded separately.

Using this procedure involves great risk of being stuck.

Under the impression of the increased risk of infection, especially AIDS-infection, through sticking injury using infected needles, various improved safety blood sample devices of the described art have been suggested in the recent years.

The present invention relates to an improved safety blood sample device of the category mentioned in the preamble of claim 1.

A blood sample device of this kind is known from U.S. Pat.No. 4.643.199. The tubular holder is axially displaced between the two end positions by using one hand to hold the safety shield and the other hand to pull or push the holder, the rear portion of which in both positions projects from the safety shield. The locking of the holder in the positions is carried out by rotating the holder relative to the safety shield, whereby some internal locking lugs on the safety shield engage corresponding transversal slots in the holder, so that further axial displacement of holder relative to safety shield is prevented.

This construction is disadvantageous for various reasons. Above all both hands are needed for the displacement of the needle holder between the two end positions and for locking it in the two positions. The working procedure of a laboratory assistant, who might be taking up to 300 blood samples per day, is thereby made more difficult and more inconvenient, as the laboratory assistant needs an unoccupied hand in a lot of situations, for instance to stop the bleeding following the removal of the needle from the vein by applying cotton, plaster etc.

Moreover the blood sample device according to the known art is provided with a very long holder, projecting from the safety shield even in the position for use, owing to the fact that the displacement and the locking of the holder relative to the safety shield is obtained by means of this projecting rear end of the holder. This end must project so far to the rear, that the laboratory assistant is able to push or pull at the holder or to rotate it gripping this projecting end. As the blood sample tubes, being mounted in this holder, during the mounting must be pressed home to ensure the penetration of the needle through the stopper in the upper end of the blood sample tube, these tubes must be a little longer than the holder, and that is the reason why the most frequently utilized short blood sample tubes cannot be used in connection with this known blood sample device. Besides this limited utility other factors come into consideration, such as the amount and price of the raw materials, the production price, the waste problems connected with the disposal after use and the weight of the device, all of which are increasing with increasing length of the holder. Moreover, the heavier the blood sample device, the more difficult it is to use, owing to the fact that periodically while taking blood samples from a patient it must repose in a tilted position on his arm, the needle being inserted in a vein, while for instance

the laboratory assistant is changing blood sample tubes.

In a blood taking device of the known art it is very difficult, too, to observe whether the rear end of the double needle is correctly positioned relative to the stopper in the upper end of the blood sample tube, whether blood is flowing into the tube, and when the tube is filled up, because the assistant has to observe these things through the two layers of the shield and the holder, this picture of observance being disturbed by the two inner axially aligned slots, and especially by the four transversal slots and the two locking lugs.

Furthermore the forward portion of the needle in the known blood taking device is not totally encapsulated by the shield in the protective position, being only protected by a removable needle shield. Following removal of this, there is a great risk of being stuck , leaving for instance an increased risk of being infected because of the no longer intact skin surface.

Still further the locking arrangement of a blood sample device of the known art is disadvantageous in being activated and deactivated by rotating the holder relative to the safety shield; the needle mounted in the bottom of the holder rotates too, and the tapering point of the needle may damage the inner side of the vein, making it more difficult to the laboratory assistant to find an intact vein next time.

Finally, owing to the described rotation being involved in this known locking arrangement one might forget to lock the holder, whereby there is a risk of unintended forward-movement of the needle.

The above mentioned disadvantages are eliminated when constructing the blood sample device according to claim 1

and claim 2. Providing the holder with a finger grip element, in the following also designated a grip, for its displacement in the safety shield brings along a number of advantages: it enables the laboratory assistant to use only one hand when working with the device; the holder might be of a substantially shorter length ensuring a wide field of application as to the length of the blood sample tubes; the weight of the device is decreased; the raw material costs and the production price are decreased and the waste problems are reduced. Since the locking arrangement is also operated by means of the grip without the need of rotating the holder relative to the safety shield, the last of the above mentioned disadvantages is eliminated, enabling the taking of blood samples in a much safer way with only a minimal risk of damaging the veins of the patient; besides the risk of forgetting to lock the holder is eliminated, as the locking takes place automatically. In this connection a further advantage of the blood sample device according to the invention should be mentioned, namely that the tapered point of the needle, in case the needle is mounted in the device during the manufacture hereof, is correctly oriented relative to the grip, so that when introducing the needle in the vein, the laboratory assistant need not search for the correct position of the needle point as it is correctly positioned from the start.

A construction of the blood sample taking device as indicated in claims 3, 4, 5 and 6 is advantageous for the following reasons:

-slot-formed openings in the safety shield enable the holding by the hand of the sample tube during the blood sample taking, always being necessary because of the pressure to the rear on the tube, being excerted by a bag-shaped membrane frequently placed on the needle,

- the blood sample taking device may be used in connection with smaller diameter tubes, often being applied when taking blood samples from children,

- a separate double or single needle may be mounted for special applications utilizing very thin or very thick needles or enabling the using up of a surplus stock of separate needles, and

- a spring activating of the needle enabling it to be quickly pushed back into the safety shield in certain situations might be advantageous.

In the following detailed description reference is made to the drawings.

Fig. 1 is a sectional view of a blood sample taking device according to the invention showing the needle in encapsulated position,

fig. 2 the same as fig. 1, but showing the needle in an intermediate position during the forward displacement of the holder,

fig. 3 the same as fig. 1, but showing the needle in its foremost projecting position, a blood sample tube being inserted,

fig. 4 is a view from above of the blood sample device, the needle being in an intermediate position,

fig. 5 is a fragmentary sectional view of a grip according to one embodiment of the invention,

fig. 6 is a view from above of a blood sample device according to the invention, showing an embodiment of the slot-formed openings in the safety shield,

fig. 7 is a fragmentary view of a blood sample device according to the invention, showing an embodiment of the further holder for small diameter tubes and a way of connecting it to the holder, and

fig. 8 is a fragmentary sectional view of a device of the invention with a screwed-in separate standard double needle.

The blood sample taking device comprises a holder 1 intended to receive an evacuated blood sample tube 2. The bottom of the holder 1 is adapted to carry a double needle 3. The holder 1 is axially displaceable in a safety shield 4 between a blood sample taking position, where the forward portion of the needle 3 is projecting from the safety shield 4, and a protective position, where the same portion of the needle 3 is totally encapsulated inside the safety shield 4. The holder 1 carrying the needle 3 can be locked in these two positions by means of locking arrangements, preferably spring-like locking arrangements. The holder 1 is provided with a finger grip element 10 on one side thereof, being movable in a longitudinal slot 11 in the safety shield 4, thereby displacing the holder 1 relative to the safety shield 4. The locking of the holder 1 in the end positions is accomplished by providing the grip 10 with an enlarged locking projection 12 and by providing the slot 11 with corresponding enlargements 13, as shown in fig. 4, without rotating the holder 1 relative to the safety shield 4. The double needle 3 can be pre-mounted in the bottom of the holder 1, or a standard needle 3 may be mounted before the blood sample taking. The rear portion of the needle 3,for penetration into the blood sample tube, may be provided with a bag-shaped membrane 6, known to those skilled in the art, this bag-shaped membrane 6 being secured to a cone ring 5. Before this rear portion of the needle penetrates the penetrable, reclosable stopper 7 of the blood sample tube

2, this portion of the needle 3 is tightly encapsulated in the bag-shaped membrane 6. When mounting a tube 2 in the holder 1, the point at the rear portion of the needle 3 at first penetrates the bag-shaped membrane 6 being pressed together towards and against the bottom of the holder 1.

When the blood sample tube is filled, and a next tube is waiting, the bag-shaped membrane 6, again tightly encapsulating the needle point, ensures that drops of blood, if any, do not leak out of the device.

The locking projection 12 at the grip 10 cannot be pushed out of the enlargements 13 in the slot 11, when a blood sample tube 2 is inserted in the device, which prevents any unintended release of the holder 1 during the application. When the tube 2 has been removed at the end of the blood sample taking, such unintended release, and reusing of the device is prevented, for instance by placing a locking arrangement at the rear portions of the holder 1 and the safety shield 4. This locking arrangement may comprise recesses 8 in the holder 1 and corresponding locking hooks 9 on the shield 4.

The safety shield 4 may be provided with openings 14, for instance longitudinal slot-formed openings as shown in fig. 6, by means of which the laboratory assistant is able to hold the tube 2 by his hand, this being recommendable when utilizing the bag-shaped membrane 6 owing to the fact that the tube 2 is pressed to the rear by the membrane.

The holder 1 may also be provided with an arrangement to receive and hold a further holder 16 for short blood sample tubes 2 with a smaller diameter, these tubes being often used when taking blood samples from children. This arrangement may for instance consist of a snap lock part 15 placed in the bottom of the holder 1, and corresponding projections on the rim of the holder 16 for engagement with the

said part 15.

The perforation in the bottom of the holder 1 may be internally threaded, for attaching a separate needle, preferably a separate standard double needle 18 correspondingly externally threaded or a separate standard single needle utilizing for instance a screwed-in standard LUER(R) adaptor, or a periferal vein catheter.

A compression spring may be positioned between the inner forward portion 22 of the shield 4 and the outer forward portion 23 of the holder so as to obtain a quick return displacement, if desired, of the holder 1 from the blood sample taking position to the protective position and making an unintended release before use of the holder 1 impossible.

When receiving the device, the position of the holder 1 relative to the shield 4 is as shown in fig. 1, the locking arrangements 8, 9 not being activated, the needle 3 anyway totally encapsulated in the shield 4 with the holder 1 in locked position, the projection 12 being situated in the rear enlargements 13 of the slot 11.

The operation of the blood sample device is as follows: The grip 10 is pressed down, thereby releasing the locking projection 12 from the rear enlargement 13 of the slot 11. The holder 1 is pushed forward as shown in fig. 2 to the forward end of the slot 11 and the grip 10 is released. The locking projection 12 is now, owing to the elasticity of the grip 10, situated in the anterior enlargement 13 of the slot 11. The grip elasticity stabilizes the holder 1 during its displacement in the shield 4 and during the blood taking procedure.

An evacuated blood sample tube 2 is then partly inserted in the holder 1, just reaching the rear point of the needle 3.

The bag-shaped membrane 6 is penetrated and pressed together. The device is now ready for use as shown in fig. 3. The forward point of the needle 3, being tapered in a sloped downward fashion relative to the grip 10, is introduced into a vein of the patient. The evacuated blood sample tube is then pushed further forward, until the needle point has penetrated the stopper 7 of the tube 2, establishing a connection between the evacuated space in the tube and the vein of the patient. A pressure difference arises, making the blood flow freely from the vein, through the needle into the tube 2. By penetrating the stopper 7 before the insertion of the needle 3 in the vein, the vacuum in the blod sample tube 2 disappears, and the blood sample drawing cannot take place. When the pressure difference is equalized, the blood will stop flowing, and the tube 2 may be removed from the device. The bag-shaped membrane automatically returns to its unfolded position, encapsulating the rear point of the needle 3. If desired a new blood sample tube may be inserted. During the taking of blood samples the stopper 7 of the blood sample tube 2 prevents the grip 10 from unintendedly being pressed down. At the termination of the blood sample taking, when the last tube 2 is filled and removed, the grip 10 is pressed down, releasing the locking projection 12 from the anterior enlargement 13 in the slot 11. The safety shield 4 is pushed forward, touching the arm of the patient, following the drawing out of the needle 3 from the vein by pushing back the grip 10 and continuing the movement to the end of the slot 11 in which position the locking hooks 9 of the shield 4 engage the recesses 8 in the holder 1. Releasing the grip 10 then brings along the insertion of the locking projection 12 in the rear enlargement 13 of the slot 11. The holder 1 is now finally secured in the shield 4, the device is in its protective position, the needle 3 being totally encapsulated in the shield 4, the disposal of the device is free of risk.

Patent Claims

1. A device for taking blood samples comprising a holder (1), being adapted to the mounting of a blood sample tube (2) and carrying or being adapted to carry a double needle (3), the holder (1) being mounted in a safety shield (4) for axial displacement relative to the said shield (4) between a blood sample taking end position in which the needle (3) projects from the shield (4), and a protected end position in which the needle (3) is completely confined in the shield (4), the holder (1) being lockable in said end positions by means of a locking arrangement (12,13) and preferably a further locking arrangement (8,9), characterized by at least one finger grip element, preferably a spring-like or spring-activated finger grip element,(10) at the holder (1), movable in a slot (11) in the safety shield (4), for axial displacement of the holder (1) in the safety shield (4) and activation of the locking arrangements (8,9 and 12,13).

2. A device according to claim 1, characterized by only one hand being used to grip the shield (4) and simultaneously to displace or lockingly engage or lockingly release the holder (1) relative to the shield (4).

3. A device according to claim 1-2, characterized by the safety shield (4) being provided with slot-formed openings (14).

4. A device according to claims 1-3, characterized by the holder (1) being provided with an arrangement (15) for adopting and attaching a further holder (16) with a smaller diameter.

5. A device according to claims 1-4, characterized by the bottom of the holder (1) being provided with

attaching means (17), preferably an internal thread in its perforation, for attaching, preferably by screwing, a separate needle, preferably a separate double needle, a separate single needle or a periferal vein catheter.

6. A device according to claims 1-5, c h a r a c t e r i z e d by at least one spring or a spring-like arrangement between the inner forward portion (22) of the safety shield (4) and the outer forward portion (23) of the holder (1).

AMENDED CLAIMS
[received by the International Bureau on 3 April 1989 (03.04.89)
original claims 1-6 replaced by
new claims 1-6 (2 pages)]

1. A single use disposable device for taking blood samples comprising a holder (1) being adapted to the mounting of a blood sample tube and carrying or being adapted to carry a double needle (3), the holder (1) being mounted in a safety shield for axial displacement relative to the said shield (4), releasable locking means (12,13) for detaining the holder in an advanced blood sample taking position, in which the needle (3) projects from the shield (4), and in a retracted position in which the needle (3) is completely confined in the shield (4), and preferably permanent locking means (8,9) operable in said retracted position of the holder (1) to permanently prohibit renewed advance of the holder (1), characterized in that said releasable locking means (12,13) comprise an outwardly spring biased element provided in the wall of the holder (1) and carrying a finger grip (10) projecting through a longitudinal guiding slot (11) in the wall of the safety shield (4), and further carrying at least one projection (12) engageable under the spring bias of said element in notches (13) in the wall of the safety shield (4) so located as to define said advanced and retracted positions of the holder (1), said retracted position of the holder (1) constituting a position of readiness assumed by the holder (1) when the device is taken into use, and from which the holder (1) can be moved to the advanced blood taking position by pressing the finger grip (10) and pushing it forward along the guiding slot (11).

2. A device as in claim 1, chareacterized in that said permanent locking means (8,9) are operable by rearward sliding of the holder (1) by means of the finger grip (10) beyond said position of readiness.

3. A device as in claim 1, characterized in that the safety shield (4) is provided with slot-formed openings (14) in lateral positions with respect to the diametrical plane defined by the guiding slot (11).

4. A device as in claim 1, characterized in that the holder (1) is provided with an arrangement (15) for adopting and attaching a further holder (16) with a smaller diameter.

5. A device as in claim 1, characterized in that the front end of the holder (1) is provided with fastening means (17), preferably a threaded hole, for the fastening, preferably by screwing, of a separate blood taking appliance, such as a separate double needle, a separate single needle or an adapter for a periferal vein catheter.

6. A device according to claim 1, characterized in that at least one compressional spring or a spring-like arrangement is provided between the inner forward portion (22) of the safety shield (4) and the outer forward portion (23) of the holder (1).

STATEMENT UNDER ARTICLE 19

In the amended claim 1, like in the original claim 1, the invention has been characterized on the background of the device of U.S. patent No. 4,643,199 which is still considered the most pertinent prior art reference. In the opening clause of claim 1 the terms "locking arrangement" and "further locking arrangement" have been replaced by the more significant terms --releasable locking means-- and --permanent locking means-- in accordance with their function as described in the respective specifications. The term "end position" has been replaced by --advanced position-- and --retracted position-- because "end position" is misleading for the retracted position, which need not be the ultimate position assumed by the holder after a single-use operation has been completed. Some consequential amendments of an editorial nature have been made in the opening clause of claim 1.

The characterizing clause has been revised so as to distinguish the finger grip arrangement of the invention more clearly from that of U.S. patent No. 4,469,110. By the finger grip arrangement as now more precisely defined in claim 1 it becomes possible to push the finger grip - and thereby the holder and the needle - in a straight path between well-defined retracted and advanced positions of arrest without any relative twisting of the holder and the safety shield. This kind of controlled translatory movement could not be obtained by the finger grip arrangement of U.S. patent No. 4,469,110 and would not fit in with the general arrangement and the purposes of the known device, which serves to thrust a pin into a user's skin by means of an actuating spring.

Claim 1 as amended also defines the retracted position of the holder as a position of readiness. As explained on page 8, line 16 ff in the description and illustrated in Fig. 1 of the drawings, this is the position assumed by the holder in the device as delivered by the manufacturer. Since in this position the needle is protected within the shield, no other safety arrangements are required to protect the user against contact with the needle, and consequently, as soon as the device has been taken out of the sterile bag, in which it is

delivered in accordance with standard practice, the user may without any preparatory handling, or manipulation of safety accessories of any kind, take the device in one hand and with the thumb of the same hand press the finger grip and push it forwards along the guiding slot to advance the holder and the needle to the position of use.

A new claim 2 has been added to define the relationship of the permanent locking means to the releasable locking means in accordance with page 9, lines 27-35 of the description.

Claims 3-6 correspond to the original claims 2-5 with amendments of an editorial nature.

Fig. 1

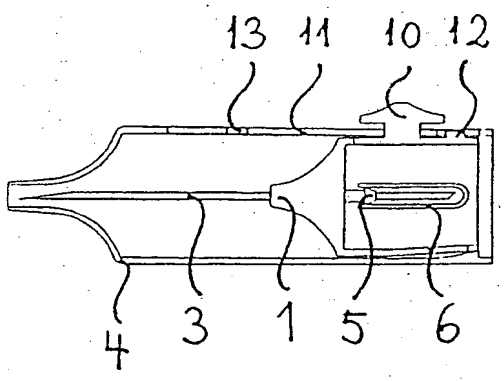


Fig. 2

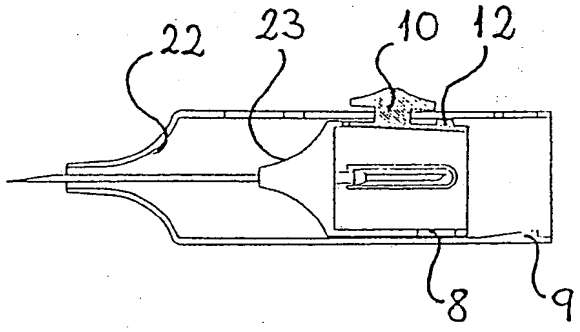


Fig. 3

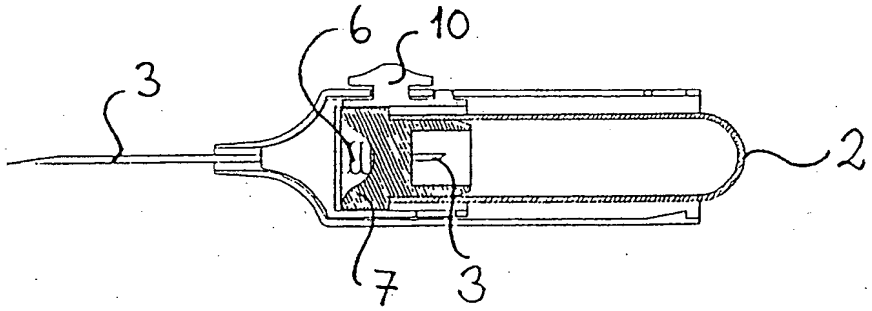


Fig. 4

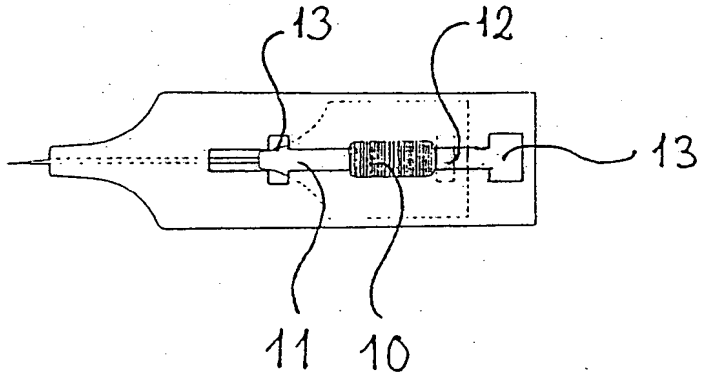


Fig. 5

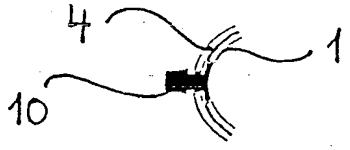


Fig. 6

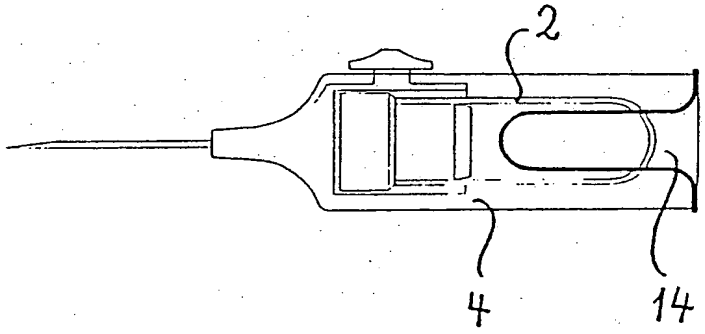


Fig. 7

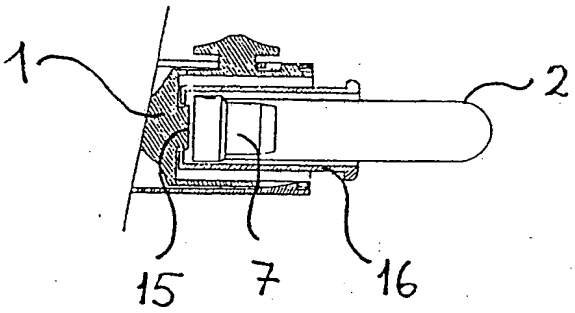
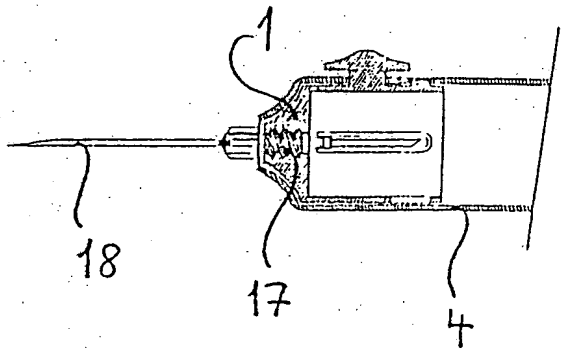


Fig. 8



INTERNATIONAL SEARCH REPORT

International Application No PCT/DK88/00186

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *

According to International Patent Classification (IPC) or to both National Classification and IPC 4

A 61 B 5/14

II. FIELDS SEARCHED

Minimum Documentation Searched 7

Classification System	Classification Symbols
IPC 4	A 61 B 5/14
US Cl	128:2F, 2G, 760, 763-767, 770; 604:181, 187, 192, 194, 198

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched 8

SE, NO, DK, FI classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT 9

Category *	Citation of Document, 11 with indication, where appropriate, of the relevant passages 12	Relevant to Claim No. 13
Y	US, A, 4 643 199 (JENNINGS,JR. ET AL) 17 February 1987 See e.g. figures.	1
Y	US, A, 4 469 110 (SLAMA) 4 September 1984 See e.g. figures details 2a, 4, 5a. & FR, 2508305 JP, 58025145 CA, 1198955	1
A	FR, A5, 2 040 830 (BEN MOURA, PIERRE) 22 January 1971	1-6
A	FR, A1, 2 564 726 (BIGGIO, ALAIN) 29 November 1985	1-6
A	US, A, 4 573 976 (SAMPSON ET AL) 4 March 1986	1-6

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
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